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DENNISON, SCHULTZ & MACDONALD
1727 KING STREET
SUITE 105
ALEXANDRIA, VA 22314

EXAMINER	
MACAULEY, SHERIDAN R	

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1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,621	CARDON, CHRISTIAAN	
	Examiner	Art Unit	
	SHERIDAN R. MACAULEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A response and amendment were received on October 7, 2008 and entered after the petition to the Office for revival was granted. All evidence and arguments have been fully considered. New claim 16 has been added. Claims 1-16 are pending and examined on the merits in this office action.

Claim Objections

Claim 11 is objected to because of the following informalities. It is recommended that the claim be amended as follows: The recitation of "their thereof" appears to be a typographical error resulting from the amendment to the claim language. It is recommended that the term be amended to "mixtures thereof". Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3, 5 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 3 and 5 are rendered indefinite by their recitation of the quantity of enzyme, such as the quantity of sulfite oxidase in claim 3 as "from approximately 0.2 IU to approximately 2000 IU." This is a relative term that renders the claim indefinite

because no units have been recited to relate this to the total composition. For example, the amount could be interpreted as from approximately 0.2 IU to approximately 2000 IU by weight of the total composition, by volume of the total composition, or per gram of the carrier material. Claim 5 uses the same indefinite language when reciting the quantity of oxidoreductase in the last two lines of the claim. Although applicant argues that IU defines the amount of the enzyme present in terms of international units and is therefore not indefinite, it remains unclear which portion of the composition applicant intends for the claimed amounts to be present. For example, the composition could comprise 10 IU of an enzyme per dose, per gram, per milliliter, or per package. Therefore, the metes and bounds of the claim remain unclear.

4. Claim 11 is rendered indefinite by the recitation of "selected from the group comprising". Because the claim uses the open language, "comprising," as opposed to the closed language, "consisting of," the metes and bounds of the Markush group recited in the claim are unclear (see MPEP 2173.05(h)).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-7 and 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery et al. (WO 94/05252) in view of Dana (US 2003/0003059 A1). Claim 1 recites a composition for the treatment of bad breath, comprising: a carrier material, a sufite oxidase enzyme, at least one enzyme capable of breaking down glucose, starch and/or cellulose present in the oral cavity, an oxidoreductase enzyme, a source of halide or pseudohalide ions, and a peroxidase enzyme, wherein the composition does not contain a substrate for the oxidoreductase enzyme. Claim 2 recites the composition according to claim 1, wherein the carrier material ranges from approximately 1% to approximately 99% by weight of the total weight of the composition. Claim 3 recites the composition according to claim 1, wherein the quantity of sufite oxidase is present in an amount of approximately 0.2 IU to approximately 2000 IU. Claim 4 recites the composition according to claim 1, wherein the enzyme capable of breaking down the starch and/or cellulose present in the oral cavity into glucose is selected from the group consisting of amylase, cellulase, glucoamylase and mixtures thereof in a quantity of from approximately 0.05% to approximately 30% by weight compared to the total weight of the composition. Claim 5 recites the composition according to claim 1, wherein the

oxidoreductase enzyme is selected from the group consisting of glucose oxidase, galactose oxidase, glycolate oxidase, aldehyde oxidase, lactate oxidase, xanthine oxidase, L-amino-acid oxidase, D-amino-acid oxidase, monophosphate oxidase, hexose oxidase, xylitol oxidase, pyranose oxidase, alcohol oxidase and mixtures thereof in a quantity of from approximately 0.2 IU to approximately 2000 IU. Claim 6 recites the composition according to claim 1, wherein the source of halide or pseudohalide ions is selected from the group consisting of potassium thiocyanate, sodium thiocyanate, ammonium thiocyanate, other thiocyanate salts, potassium iodide, other iodide salts, sodium chloride, other chloride salts and mixtures thereof in a quantity of from approximately 0.0001 mol/g to approximately 0.1 mol/g of carrier material. Claim 7 recites a composition according to claim 1, wherein the peroxidase is selected from the group consisting of lactoperoxidase, superoxide dismutase, myeloperoxidase, chloroperoxidase, horseradish peroxidase, saliva peroxidase and mixtures thereof, and in a quantity of from approximately 0.1 IU/g to approximately 100 IU/g of the carrier material. Claims 9 and 16 recite the composition according to claim 1, further comprising a buffering agent used to obtain a composition with a pH of from approximately 4 to approximately 8, specifically from approximately 5.4 to approximately 6.5. Claim 10 recites the composition according to claim 1, wherein it contains an antibacterial enzymatic agent selected from the group comprising lysozyme, lactoferrin and their mixtures. Claim 11 recites the composition according to claim 1, further comprising a flavoring agent selected from the group consisting of chicken flavors, fish flavors and mixtures thereof. Claims 12-15 recites the compositions according to claim

1, further comprising suitable vehicles and excipients for oral administration, wherein it is supplied in a liquid oral form, a solid oral form, or in the form of toothpaste, chewing strips, chewing gum, mouthwash, oral gel, dental powder, chewing tablet, or chewing paste.

8. Montgomery teaches a chewable composition for animal feedstuff which may comprises a carrier material, a oxidoreductase (such as sulfite oxidase or glucose oxidase), a halide or pseudohalide ion (such as potassium thiocyanate), and a peroxidase (such as lactoperoxidase; abstract, p. 9, par. 2, p. 12, par. 2, p. 13, par. 3). Montgomery teaches that the oxidoreductase may be present at concentrations of between 5 to 50 enzyme units per gram of carrier, that the halide or pseudohalide may be present at a concentration of 0.1 moles per gram of carrier, and that the peroxidase enzyme may be present at a concentration of from 10 to 100 enzyme units per gram of carrier (p. 10, par. 2, p. 13, par. 1-3). Montgomery teaches that the composition may comprise a chicken flavor and that it may be supplied in a solid oral form, such as a chewing strip (p. 21, example 2). Although Montgomery teaches that a buffer may be added to the composition to ensure the optimal pH for enzymatic activity (p. 12, par. 1), Montgomery does not teach that the composition is buffered within the claimed pH range. Montgomery does not specifically teach compositions that also comprise an amylase or a cellulase as a glucose-, starch- or cellulose-degrading enzyme or lysozyme or lactoferrin as an antibacterial agent, or that are formulated as a liquid.

9. Dana teaches oral care compositions which may comprise cellulase to prevent plaque and lysozyme as an antimicrobial agent (abstract, p. 6, par. 61, 62). Dana

teaches that the oral care composition may be formulated in any oral form, such as a solution (liquid) or chewable tablet (p. 3, par. 33).

10. At the time of the invention, an oral care composition comprising nearly all of the claimed elements was known, as taught by Montgomery. It was further known that oral care compositions could comprise cellulase and lysozyme, and could be formulated in a number of different manners, as taught by Dana. One of ordinary skill in the art would have been motivated to combine these teachings because Montgomery teaches that the compositon should comprise ingredients that are antimicrobial and treat plaque (abstract, p. 2, par. 3), and Dana teaches that lysozyme and cellulase are two such components. Thus, the prior art included each of the claimed elements, which applicant has combined to yield the claimed invention. It was known in the art that many elements could be combined in oral care compositions to yield predictable results, as taught by Montgomery and Dana, both of whom teach that the combination of numerous agents in oral combinations was common in the art at the time of the invention. It would therefore have been obvious for one of ordinary skill in the art to combine these components to arrive at the claimed composition. Although the claims recite that the composition does not contain a substrate for an oxidoreductase enzyme, it is noted that Montgomery teaches that the composition may be prepared in the absence of the substrate, and that the substrate may be added afterwards as a coating or granule (p. 23, line 3-p. 24, line 11); therefore, the application teaches the preparation of a composition that does not contain a substrate for the oxidoreductase enzyme. Furthermore, the preparation of similar compositions that did not comprise substrates

for oxidoreductase enzymes were known in the art at the time of the invention (see, for example, Dana at p. 8, example 1). Regarding the inclusion of both sulfite oxidase and another of the claimed oxidoreductases, such as glucose oxidase, in the composition, both of these enzymes are taught by Montgomery to be useful for the same purposes, i.e. for use as an oxidoreductase in the antimicrobial composition; it would have been obvious for one to combine two components that were known in the art at the time of the invention to be useful for the same purpose (see MPEP 2144.06). Furthermore, it would have been a matter of routine optimization to use the carrier material in the claimed concentration in composition and to use a buffer that worked within the claimed pH range, as evidenced by Dana, who teaches the desirability for optimization of components in the oral care compositions, and Montgomery, who teaches the desirability to optimize the pH within the range necessary for enzyme function. One of ordinary skill in the art would have had a reasonable expectation of success in combining these teachings to arrive at the claimed invention because each of the references teaches that the components are compatible with a multi-component oral care composition that is suitable for administration to subjects. It would therefore have been obvious for one of ordinary skill in the art to combine the references discussed above to arrive at the claimed composition.

11. Claims 1-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery et al. (WO 94/05252) in view of Dana (US 2003/0003059 A1) as applied to claims 1-7 and 9-16 above, and further in view of Chaykin (US 6,090,402). Claims 1-7

and 9-15 are discussed above. Claim 8 recites the composition according to claim 1, wherein the composition further comprises an agent stimulating salivation, selected from the group consisting of saturated or unsaturated emulsifiers, acidifiers and their mixtures.

12. The teachings of Montgomery and Dana are discussed above. At the time of the invention, it would have been obvious to combine the teachings of Montgomery and Dana to arrive at a composition which comprises nearly all of the claimed elements, as discussed above. Neither of the references, however, teaches compositions comprising an acidifier or an emulsifier as an agent stimulating salivation.

13. Chaykin teaches an oral composition that may use an acidifier, such as citric acid, and/or the mastication produced by chewing as a salivary stimulant (col. 2, par. 15-42).

14. At the time of the invention, a composition comprising nearly all of the claimed elements would have been obvious in view of Montgomery and Dana. It was also known at the time of the invention that acidifiers could be added to oral care compositions for the stimulation of saliva production, as taught by Chaykin. One of ordinary skill in the art would have been motivated to combine these teachings by combining the acidifier taught by Chaykin with the composition of Montgomery and Dana because Montgomery teaches that components of the composition become active when they are combined with saliva (abstract). Although Montgomery teaches the use of mastication to produce saliva (abstract), one of ordinary skill in the art would have recognized that the production of saliva could have been further enhanced by the

addition of the acidifier of Chaykin. One of ordinary skill in the art would have been had a reasonable expectation of success in combining these teachings because Chaykin teaches that the acidifier is compatible with an oral care composition for administration to subjects. It would therefore have been obvious to combine the teachings discussed above to arrive at the claimed invention.

15. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

16. Applicant's arguments filed October 7, 2008 have been fully considered but they are not persuasive. Applicant argues that the prior art does not teach or render obvious the claimed composition because the references do not teach compositions that do not contain a substrate for an oxidoreductase enzyme. In response to this, however, it is noted that, Montgomery teaches that the composition may be prepared in the absence of the substrate, and that the substrate may be added afterwards as a coating or granule (p. 23, line 3-p. 24, line 11); therefore, the application teaches the preparation of a composition that does not contain a substrate for the oxidoreductase enzyme. Furthermore, the preparation of similar compositions that did not comprise substrates for oxidoreductase enzymes were known in the art at the time of the invention (see, for example, Dana at p. 8, example 1). Thus, the element recited in the claims is taught by the cited prior art.

17. Applicant further argues that the specific components included in the compositions of the prior art are not incorporated for the same functions as they serve in the composition of the instant claims. However, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Thus, although applicant includes, for example, lactoperoxidase as an antibacterial component rather than for the reasons it is included in the compositions of the prior art, the additional advantage does not render the claimed subject matter patentable. Furthermore, although applicant argues that sulfite oxidase is not exemplified as a component for use in the composition of Montgomery, the inclusion of both sulfite oxidase and another of the claimed oxidoreductases, such as glucose oxidase, in the composition, would have been obvious because, as discussed in the rejections above, both of these enzymes are taught by Montgomery to be useful for the same purposes, i.e. for use as an oxidoreductase in the antimicrobial composition, and were known in the art at the time of the invention to be useful for the same purpose. Thus, the claimed invention is rendered obvious by the cited teachings of the prior art.

18. Therefore, applicant's arguments have been fully considered, but they have not been found to be persuasive.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

SRM